Comment to: Draft Guidelines for the Prevention of Intravascular Catheter-Related Infections

Thank you for the opportunity to comment on the 2009 "Draft Guidelines for the Prevention of Intravascular Catheter-Related Infections" ("The Draft"). This letter comments on one recommendation relating to "Needleless Intravascular Catheter Systems" (page 47, line 1064), number 6 (lines 1078 and 1079) and on p. 74, lines 1612-1613. This Category II recommendation states "When needleless systems are used, the split septum valve is preferred over the mechanical valve due to the risk of infection".

While unintentional, the consequences of this recommendation will: (1) be to encourage clinicians to "stereotype" devices based on specific design features rather than the available scientific evidence which focuses on an analysis of the device as a whole; (2) increase the potential risk of thrombotic catheter occlusion and sharps injuries to healthcare workers if clinicians revert to a first generation split-septum device; and (3) increase the rate of catheter-related bloodstream infections ("CRBSI") and the resulting unfavorable patient outcomes by encouraging clinicians to ignore available research on and the importance of practice bundles.

The first generation needleless connector, the Interlink® "split-septum", is a multi-piece system that requires an external blunt cannula and split-septum injection site (BCSS). The 'split-septum' is simply a feature of the BCSS and does account for the required blunt cannula which makes up the complete system and its ability to prevent bacterial ingress. Likewise, the term "mechanical valve" also represents a feature, or characteristic of a device, yet ignores how ALL the components of a device interact specifically to protect against bacterial ingress.

The term "split-septum" has been used by a certain manufacturer to promote their needleless connectors for the prevention of CRBSI. The promotion is based on this one feature while there is a complete absence of scientific or clinical evidence to support their actual product. In essence the manufacturer is using the 'tire' to say their 'car' is safe and effective. While in fact, the available scientific and clinical evidence cited in The Draft and discussed here, does not support any single feature of a device.

More technically advanced luer-activated devices ("LAD") have addressed the inherent risks associated with BCSS systems including thrombotic catheter occlusion and needlestick injury resulting from poor user compliance. LADs may be described as standalone products which do not require external components for use. LADs have subsequently been erroneously lumped by The Draft's recommendation into a category of "mechanical valves" implying that all LADs have equivalent risk associated with their use. The numerous LADs differ widely in design features, most importantly the access site, flow path configuration, and fluid displacement profile. Essentially, the proposed recommendation would elevate the split-septum feature over ALL alternative features and technologies without discrimination or sound scientific foundation, discounts consideration of the use of a device with incorporated safety technology and flies in the face of recent studies indicating the importance of implementing practice "bundles" to eliminate CRBSI.

The recommendation is NOT supported by the four studies cited as support in the Draft. i.e., Maragakis (338), Rupp (336), Salgado (337) or Field (339). Maragakis demonstrates the superior performance of the CLAVE® over the Smartsite® Plus, both being modern LADs (Maragakis (338)). Rupp and Salgado demonstrate the superior performance of the BCSS over the Smartsite and Smartsite Plus LADs (Rupp (336) and (Salgado (337)). Field purports to involve the CLAVE® and CLC2000® LADs, although it is unclear on this point as it specifically references and depicts only two devices, the Interlink and the CLC2000 (Field (339)).

Notably, all four of the referenced studies are retrospective, non-controlled, non-randomized observational studies from single study sites that lack precision and demonstrate at best an association, which is a much lower level of reliable evidence than causation. Importantly, the conclusions drawn in these studies can only be made for the comparisons between the specific devices used in each study and ***cannot*** be generalized to any other needleless connector or feature of a device. At best, these studies suggest that: (1) the range of CRBSI rates experienced when using the BCSS is highly variable ranging from 1.79 to 5.59 per 1000 catheter days and unacceptably higher than the desired goal of zero (2) use of the Smartsite and Smartsite Plus can lead to unacceptably high levels of CRBSIs ranging from 5.95 to 10.64 per 1000 catheter days; and (3) the CLAVE is associated with a lower infection risk (1.5 per 1000 catheter days) than the BCSS (1.79 to 5.59 per 1000 catheter days.

The Rupp, Salgado and Field studies also lead to the inescapable conclusion that the needleless connectors studied were not fully responsible for the observed CRBSIs. In part, this is demonstrated by the variable rates of CRBSIs associated with the devices. BCSS range from 1.7 to 5.59 per 1000 catheter days, and the LAD from 2.4 to 10.64 per 1000 catheter days. In the absence of other factors affecting the observed rates of CRBSIs, this range should have been narrower. The cited studies do not reflect the current level of "best practices" arising from the growing sophistication of healthcare facilities on the subject of CRBSI prevention. More recently, the emphasis of healthcare facilities has shifted to the introduction of practice "bundles" to help prevent the incidence of CRBSIs (Provonost). Berenholtz et al. was the first to report a zero CRBSI rate in intensive care units with the implementation of a CRBSI prevention "bundle" where the CLAVE was in use.

The Draft ignores numerous and more recent studies demonstrating the efficacy of various LADs in a clinical setting (Moore, Perago and Harnage), and in vitro studies that have examined the ability of various LADs to prevent microbial ingress (Ryder and Yebenes). None of these studies support the proposed recommendation that "split-septum," or any other single feature of a device may reduce CRBSIs or lead to zero CRBSIs.

Contrary to the result that one might expect from The Draft's recommendation, a recent study by Garcia et al. has shown no statistically significant difference in the rate of CRBSIs with the use of the Interlink BCSS compared to the Flolink®, a LAD with positive pressure. For patients with central lines, the rates were 1.16 in the BCSS group and 1.15 per 1000 catheter days in the LAD group. While no statistically significant differences in infection rates were observed between the two patient groups, the BCSS group experienced four sharps injuries and the LAD group experienced none. Disappointingly, the recommendation in favor of BCSS fails to account not only for the higher rate of sharps injuries (Garcia)

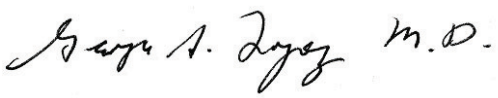
but also the risk of increased catheter occlusion (Salgado) occasioned through the use of the BCSS devices. Catheter occlusion is a major and frequent complication in the use of vascular catheters. The preference of the BCSS device will surely increase the rate of catheter occlusion and the subsequent poor outcomes of delayed therapy, catheter removal, increased use of fibrinolytics and increased costs.

The only known and clearly erroneous support for the "efficacy" of a split-septum feature can be found in a soon to be published, article (Jarvis). In this cohort study, the mean value for CRBSI's associated with BCSS was 3.8 (the "study" mixes the results of four BCSS trials with a report involving needles for some unexplained reason). The range of CRBSI rates for the BCSS was 2.29 to 8.17. All of these rates are higher than those commonly accepted today in the healthcare community and substantially higher than the rates currently being reported and involving more modern LADs (Moore, Perago, Harnage). Surprisingly, the "study" relies upon results that are admittedly not "statistically significant." The issue of conflict of interest in relation to professional conduct in association with industry was raised. Of note is the relationship of two of the authors as consultants and one author as an employee of the manufacturer of BCSS products that also promotes the "split-septum" as a feature which can reduce the risk of CRBSI.

Based on the above, we request that the proposed recommendation, "When needleless systems are used, the split septum valve is preferred over the mechanical valve due to increased risk of infection," not be adopted. In today's heavily litigious environment, health care providers may feel compelled to change from their existing needleless connector, despite what may be an excellent performance history, solely to protect themselves from claims that their failure to adhere to "best practices" contributed to a costly medical intervention or a more tragic patient death. Ironically, a change to a less effective needleless connector may offer a hospital a better legal defense, while resulting in substantially more healthcare worker and patient harm.

Instead, the clinician should be required to review the published scientific literature and consider each unique device as a whole, without an unfounded reliance upon a single feature or the mistake of using "stereotypes". Proceeding in this fashion will likely have two results: 1) Clinicians will use science in device selection, rather than be swayed by the Marketing tactics of certain companies; and, 2) manufacturers of these products will be forced to pursue scientific foundation to promote their products and develop new products with enhanced safety features.

Respectfully yours,



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